NOV - 9 2011

K111097

3. 510(k) Summary

Prepared:	April 15, 2011
Applicant / Sponsor:	Fx Solutions 1663 rue de Majornas 01440 Viriat France
Manufacturer:	Compagnie Financière & Médicale 13 Bd Victor Hugo 01000 Bourg En Bresse France
Contact:	Jean-Jacques Martin +33 4 74 55 35 55 www.fxsolutions.fr
Proprietary Name:	Humelock Cemented Shoulder Prosthesis
Common Name:	Hemi-Shoulder Replacement System
Classification Name:	21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis, Class II
Product Codes:	HSD
Substantially Equivalent Devices:	K992525 - Acumed Modular Shoulder System K992065 – DePuy Global Advantage Shoulder

Device Description:

The Humelock Cemented Shoulder Prosthesis is a hemi-shoulder prosthesis consisting of a humeral stem and a humeral head.

The humeral stem is manufactured from Ti-6Al-4V alloy conforming to ISO 5832-3 and is available in diameters of 6-15mm. The distal end of the humeral stem is cylindrical with a polished surface. The proximal portion of the humeral stem has a grit blasted surface.

The humeral stem incorporates a male taper for attachment of the humeral head.

The humeral head is manufactured from wrought Co-Cr-Mo alloy conforming to ISO 5832-12 and is available in diameters of 39 – 50mm with heights of 14 – 19mm in centered and offset styles. The offset of the taper allows the head to be rotated relative to the cut surface of the humerus to provide optimal coverage of the bone. A female taper allows attachment to the humeral stem.

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Intended Use / Indications:

The Humelock Cemented Shoulder Prosthesis is indicated for use in hemi-shoulder replacement to treat:

1. Proximal humeral fractures
2. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis;
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a previously implanted primary component, a humeral plate or a humeral nail).

The Humelock Cemented Shoulder Prosthesis is intended for cemented use only.

Summary of Technologies/Substantial Equivalence:

Substantial equivalence of the Humelock Cemented Shoulder Prosthesis to the predicate devices is based on a comparison of indications, intended use, materials, design and sizing.

Non-Clinical Testing:

Mechanical testing was conducted to demonstrate the stability of the modular connection between the modular heads and the humeral stem.

Clinical Testing:

Clinical testing was not necessary to determine substantial equivalence between the Humelock Cemented Shoulder Prosthesis and the predicate shoulder systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Fx Solutions
% Mr. Jean-Jacques Martin
1663 rue de Majornas
01440 Viriat
France

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Re: K111097
Trade/Device Name: Humelock Cemented Shoulder Prosthesis
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: October 24, 2011
Received: October 27, 2011

Dear Mr. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K111097

Device Name: Humelock Cemented Shoulder Prosthesis

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Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111097